K122818

510(k) Summary
for the
Olympus MAJ-172
Instrument Tray for LTF Videoscope
(per 21CFR 807.92)

JAN 4 2013

1. SUBMITTER/510(K) HOLDER

KeyMed (Medical & Industrial) Ltd.
Stock Road
Southend-On-Sea
Essex SS2 5QH
United Kingdom

2. CONSULTANT/CONTACT

Aptiv Solutions Inc.
11440 West Bernardo Drive, Suite 300
San Diego, CA 92127
Telephone: 858-753-1961
Facsimile: 858-753-1962

Primary Contact: Ron Warren
Date Prepared: October 15, 2012

3. DEVICE NAME

Proprietary Name: Olympus MAJ-172 Instrument Tray for LTF Videoscope
Common/Usual Name: Sterilization container
Classification Name: Sterilization wrap, containers, trays, cassettes and other accessories

4. PREDICATE DEVICES

- Olympus Sterilization Trays (K033222)
- Gyrus ACMI Flexible Endoscope Storage-Sterilization Tray (K092682)

5. DEVICE DESCRIPTION

The Olympus MAJ-172 Instrument Tray for LTF Videoscope is a polymer tray with a perforated lid intended to secure an endoscope and accessories during exposure to gaseous sterilization methods.

6. INDICATION FOR USE/INTENDED USE

The Olympus MAJ-172 Instrument Tray for LTF Videoscope is intended to be used to enclose Olympus medical devices including hand instruments, trocars, camera heads, adapter, and endoscopes to be sterilized by a health care provider. It is intended to allow steam or ethylene oxide sterilization of the enclosed medical device. The Olympus MAJ-172 Instrument Tray for LTF Videoscope is a purpose designed transport and sterilization case indicated for use in medical facilities to accommodate an endoscope from the Olympus LTF range of videoscopes, plus certain identified accessories, for reprocessing by autoclaving (steam) or ETO sterilization (depending on the model). LTF Type 160 and VH videoscopes are compatible with Steam and ETO sterilization cycles. LTF Type V3 and VP are compatible only with ETO sterilization cycles.

The Olympus MAJ-172 Instrument Tray for LTF Videoscope is designed to secure and store a single videoscope and its accessories for sterilization at a healthcare facility. Refer to the instrument tray instructions for use for the proper orientation of the videoscope and accessories within the instrument tray. The recommended sterilization cycles for the LTF videoscopes are as follows:

ETO Sterilization:	Steam Sterilization:
100% ETO concentration: 735 mg/L	Vacuum: 0.016 MPa minimum
Temp: 57 °C	Pressure: 0.101 MPa minimum
Relative Humidity: 70%	Temp: 135 °C
Processing (Hold) Time: 1 hour	Exposure Time: 3 minutes
Aeration Time: 12 hours	Drying Time: 20 minutes

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The Olympus MAJ-172 Instrument Tray for LTF Videoscope has identical technological characteristics compared to the Olympus Sterilization Trays (K033222) which are cleared for steam sterilization of endoscopic devices and accessories. . The sterilization trays are made of the high performance thermoplastic Polyphenylsulfone [PPSU (RADEL®)], each consisting of a natural colored lid, including four stainless steel clips and two stainless steel handles, as well as of a beige base with middle-blue

multipoint silicone stripes and a laser marking. Each tray is customized for specific instruments, which ensures their safekeeping during sterilization, storage and transportation. The instrument trays do not require any maintenance and service and have an expected useful life of five years.

The Olympus MAJ-172 Instrument Tray for LTF Videoscope is also similar to the Gyrus ACMI Flexible Endoscope Storage-Sterilization Tray (K092682) which is constructed of Radel-R Polyphenylsulphone and cleared for ETO sterilization of Gyrus flexible endoscopes. Under K092682, the Gyrus storage-sterilization tray was found substantially equivalent to the Olympus Sterilization Trays (K033222). The clearance allowed for the use of ETO sterilization while the predicate device was cleared for steam sterilization only. The Olympus MAJ-172 Instrument Tray for LTF Videoscope is intended for both ETO and steam sterilization methods (depending on the endoscope model).

8. Summary of Non-clinical Performance Testing as Basis for Substantial Equivalence

A series of non-clinical studies were completed to assess the performance of the Olympus MAJ-172 Instrument Tray for LTF Videoscope. These included simulated use tests, drop testing, resistance to chemicals, cleaning, steam sterilization and ethylene oxide sterilization studies. The device met the requirements of all required design specification testing.

9. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was conducted or required in support of this premarket clearance notification.

10. Summary of other Information

This submission included comparison of intended use statements, proposed product labeling and summary information and labeling on predicate devices.

11. Conclusions Drawn From Non-clinical and Clinical Tests

Based on the information provided in this 510(k), KeyMed believes that the proposed sterilization tray is substantially equivalent to the previously cleared Olympus instrument trays. The proposed device is one of a family of Olympus sterilization trays already cleared and marketed for steam sterilization. The Olympus MAJ-172 Instrument Tray for LTF Videoscope is also substantially equivalent to the Gyrus storage-sterilization tray which is comprised of a similar Polyphenlysulfone

thermoplastic and is cleared for ETO sterilization of several models of Gyrus flexible endoscopes. The proposed device raises no new issues of safety and effectiveness. The non-clinical testing performed demonstrates that the proposed device met all test specifications and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 4, 2013

KeyMed (Medical & Industrial Equipment) Limited
C/O Mr. Ronald S. Warren, RAC
Director, Medical Device Regulatory Services
Aptiv Solutions, Incorporated
11440 West Bernardo Court, Suite 300
SAN DIEGO CA 92127

Re: K122818
Trade/Device Name: Olympus MAJ-172 Instrument Tray for LTF Videoscope
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: December 3, 2012
Received: December 4, 2012

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

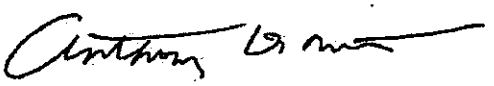
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122818

Device Name: Olympus MAJ-172 Instrument Tray for LTF Videoscope

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Prescription Use ___ AND/OR Over-The-Counter Use _x_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.01.02 16:49:24 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____